



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/925,627	09/09/1997	DENISE FAUSTMAN	00786/036005	5849

21559 7590 09/10/2003

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

SCHEINER, LAURIE A

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/925,627

Applicant(s)
Faustman

Examiner
Laurie Scheiner

Art Unit
1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 23, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36, 41-43, 57, 59, 60, and 89-97 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36, 41-43, 57, 59, 60, and 89-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 23, 26 6) ☐ Other:

Art Unit: 1648

Claims 36, 41-43, 57, 59, 60 and 89-97 are pending in this application.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 89-91 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention and as failing to provide an adequate written description of the invention and failing to present the best mode contemplated by the applicant for carrying out his invention for reasons of record.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36, 41-43, 57, 59, 60 and 92-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stock et al. (Journal of Surgical Research **46**, 317-321 (1989)) for reasons of record.

Applicant's arguments filed January 23, 2003 have been fully considered but they are not persuasive.

In response to applicant's argument that the reference(s) fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., applicant's discovery that $F(ab)_2$ -masked islet cells of one species could be successfully transplanted into

Art Unit: 1648

an animal of a different, unrelated species without rejection) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Neither the F(ab)₂-masked islet cells, nor the method of successful transplantation are recited by the claims. Although a motivation can be applied in a rejection of a composition claim, it is noted that a method of successful transplantation is not required to meet the limitations of the instant composition claim. That is, with respect to the rejection set forth under 35 U.S.C. 103(a) Applicants argue that their results could not have been predicted by Stock et al., and Stock et al. carried out *in vitro* experiments. As argued, it could not have been predicted that instant F(ab)₂ masking would allow successful, long term transplantation of foreign tissue into a living animal without humoral immune system-mediated rejection.

The examiner notes that the claims are not limited to that which is argued. Moreover, the claims are broadly drawn to compositions, and not an *in vivo* method of transplantation. Applicants acknowledge Stock et al.'s. masked islet cells. However, applicants assert that the results showing abrogation of the CTL response were measured in the extreme short term. The examiner contends that antibody disassociation over time is not relevant with respect to the instant composition claims. That is, either the composition is taught by, or obvious over, Stock et al., or the composition is neither taught nor obvious over Stock et al.

Applicants argue that Stock et al. employed intact antibodies, which cannot be used *in vivo* since the Fc portion would fix complement. The examiner contends that the instant claims do not exclude intact antibodies. Moreover, applicants have previously argued (response of February 15, 2001) that the composition claims are entitled to the instant breadth since intact

Art Unit: 1648

antibodies are disclosed in the specification as a masking agent. Thus, applicant's arguments appear to be inconsistent.

Applicants argue in support of a proper written description with respect to guidance as to making and using a genetically engineered cell. Applicant's arguments are not convincing since the teachings of the disclosure are directed to islet cell masking, which would be voided by lack of antigen expression in the transgenic. It is well settled that the claimed subject matter need not be supported by an explicit, word for word recitation, but something more than a suggestion is needed to satisfy the requirement for an adequate written description. As set forth in Lockwood v. American Airlines Inc., 107 F.3d 1565, 1571-1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997):

It is the disclosures of the applications that count. Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. While the meaning of terms, phrases, or diagrams in a disclosure is to be explained or interpreted from the vantage point of one skilled in the art, all the limitations must appear in the specification. The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought. . . [A]ll that is necessary to satisfy the description requirement is to show that one is "in possession" of the invention . . . One shows that one is "in possession" of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. . . Although the exact terms need not be used in haec verba, . . . the specification must contain an equivalent description of the claimed subject matter. [Citations omitted]

It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose. Each application must describe the claimed features.

Art Unit: 1648

That the specification must contain a written description of that which is now claimed. Fiers v. Revel, 984 F.2d 1164, 1170, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993).

Whether the disclosure relied on “reasonably convey [] to the artisan that the inventor had possession at that time” of that which is now claimed is a question of fact.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

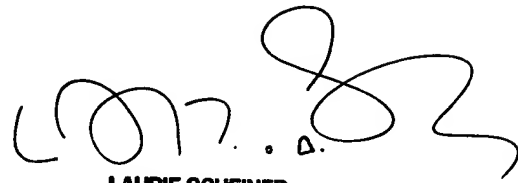
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number:

Art Unit: 1648

(703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.


Laurie Scheiner/LAS
September 5, 2003


LAURIE SCHEINER
PRIMARY EXAMINER